CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS

Release Date: July 25, 2001

RFA: RFA-AR-01-009

National Center on Minority Health and Health Disparities
National Center for Research Resources
National Eye Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Drug Abuse

Letter of Intent Receipt Date: December 17, 2001
Application Receipt Date: February 15, 2002

PURPOSE

The National Center on Minority Health and Health Disparities (NCMHD) joins the National Center for Research Resources (NCRR), the National Eye Institute (NEI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Aging (NIA), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Institute of Drug Abuse (NIDA) to invite minority institutions with professional schools offering doctoral degrees in one or more of the health care disciplines to apply for a clinical research education and career development grant.

The purpose of this Clinical Research Education and Career Development (CRECD) award is to support the development and implementation of curriculum-dependent programs in minority institutions to train selected doctoral and postdoctoral candidates in clinical research leading to a Master of Science in Clinical Research or Master of Public Health in a clinically relevant area. A successful program will result in an accredited Master's degree program and will produce well-trained clinical researchers who can lead clinical research projects.

Applications for a one year planning grant were solicited through a previous RFA (AR-00-009). However, holding a planning grant is not a prerequisite for applying under this RFA.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

A. Minority Institution. The applicant institution must be a domestic, non_Federal organization, such as a medical, dental, nursing or pharmacy school with graduate education programs, or a comparable institution with graduate education programs, or a research institution that has ongoing clinical research and clinical research training programs. The applicant institution must be accredited to award master and doctoral graduate degrees. Foreign institutions are not eligible for the Clinical Research Education and Career Development grants.
Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

The applicant institution must serve students from minority ethnic groups underrepresented in the biomedical sciences (e.g., African Americans, Hispanics, American Indians, Alaskan Natives, Native Hawaiians, and Pacific Islanders) comprising a majority (more than 50%) of the institution's enrollment. The applicant institution must have faculty and facilities for the proposed program and must conduct ongoing clinical research. The institution must demonstrate the commitment and capability to develop a core curriculum leading to an accredited Master of Science in Clinical Research degree or an accredited Master of Public Health degree in a clinically relevant area. An institution may submit only one application. Applicants are encouraged to develop consortia in common geographic locations to enhance the depth of their faculty and participant pools, or to improve the quality of the educational experience.

B. Students. The goal is to promote the development of well-trained clinical researchers who can lead clinical research studies addressing health disparities among the American people. The institution must document a cadre of doctorally qualified individuals to enroll in the proposed

program. Doctorally qualified individuals are those who have completed a doctoral degree or are in the final phase of completing a doctoral degree. All students must be U.S. citizens, non-citizen nationals or lawfully admitted permanent residents of the U.S. The program can include as students junior faculty, post-doctoral trainees such as interns and residents, and doctoral candidates who seek to combine their clinical doctorate degree with a Master of Science in Clinical Research or a Master of Public Health in a clinically relevant area. Relevant clinical doctorate degrees include: M.D., D.D.S., D.M.D., D.O., D.C., O.D., N.D. (Doctor of Naturopathy), doctorally prepared nurses, Ph.D. with clinical responsibilities, or Pharm.D. Those individuals with a Ph.D. who want to become involved in clinical research may also participate.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) R25 educational project grant mechanism. The applicant will be responsible for the planning and direction of the proposed program. The principal investigator and a co-director from each awardee institution will meet twice a year with NIH staff to review program development. The total project period for an application submitted in response to this RFA may not exceed 5 years. This RFA is a one-time solicitation. The anticipated award date is September 1, 2002.

FUNDS AVAILABLE

A total budget for FY 2002 of approximately $2.7 million will be committed to fund applications submitted in response to this RFA. An applicant may request a project period of five years and a budget for direct costs of up to $500,000 per year. It is anticipated that approximately 5 awards will be made in FY 2002. This funding level is dependent upon the receipt of a sufficient number of meritorious applications.

OBJECTIVES

Background

As part of the Federal effort to eliminate racial and ethnic disparities in health, a need has been identified to expand the training of clinical researchers at minority institutions as one approach to fostering careers in clinical research addressing health disparities. Minority institutions conduct high quality programs for educating ethnic minorities, and they represent a rich resource of talent with the appropriate cultural sensitivity and perspectives needed in clinical research. However, minority institutions have had difficulties developing and sustaining independent clinical research,

and there is a paucity of ethnic minority clinical researchers who are pursuing successful clinical research careers. There is a critical need for properly trained clinical researchers in certain health areas that disproportionately affect minority and underserved populations. Programs that include training specific to the unique knowledge, skills, and challenges needed to conduct clinical research in these areas are strongly encouraged. These include drug abuse and addiction and dental health.

The scope of clinical research is broad. Clinical research has been defined in the NIH Director's Panel on Clinical Research Report (Nathan Report) of December 1997 (see http://www.nih.gov/news/crp/97report/index.htm).
This report states that "Clinical research includes a) patient_oriented research, b) epidemiologic and behavioral studies, and c) outcomes research and health services research. Patient_oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes: a) mechanisms of human disease; b) therapeutic interventions; c) clinical trials; and d) development of new technologies. Excluded from this definition are in vitro studies that utilize human tissues but do not deal directly with patients."

The NCMHD, NCI, NCRR, NCCAM, NEI, NIA, NIAID, NIAMS, NIDCR, NIDDK, NIDA, and NINR teamed to promote the first step in fostering the development of curricula in clinical research leading to a masters degree at minority institutions through RFA AR-00-009 for a one year planning grant in FY 2001.

This RFA AR-01-009 is the second phase for development of curricula in clinical research leading to a masters degree at minority institutions. However, it is not necessary for an institution to have held a planning grant to apply for this RFA.

Program: The award provides 5 years of support to a minority institution for a Clinical Research Education and Career Development (CRECD) program. The principal investigator leads a Curriculum Advisory Committee to design, develop, implement and evaluate a curriculum for an accredited Master of Science in Clinical Research or an accredited Master of Public Health in a clinically relevant area. The award provides partial support for these activities and for external consultants and advisors. The award also provides for partial salaries and stipends of doctoral and postdoctoral trainees and for other program_related research costs. The CRECD program must include a curriculum-based, multi-disciplinary didactic and collaborative training for clinical research and for collaborative clinical research experiences for trainees to enhance clinical

research skills. Programs that include training specific to the unique knowledge, skills, and challenges needed to conduct clinical research in drug abuse and addiction and other behavioral clinical research are encouraged.

Environment: The participating institution(s) must have well_established clinical research programs and faculty qualified in curriculum development, implementation and program evaluation to serve as faculty for the program. The institution must demonstrate a commitment to provide sustained leadership and dedicated faculty time to the development and implementation of the program; and commitment to the development of clinical investigators as productive, independent clinical investigators.

D. Allowable costs:
No application may exceed $500,000 in direct costs.

1. Salary: The principal investigator can request salary support for leadership, management, coordination and evaluation of the Clinical Research Education and Career Development (CRECD) Program, in accordance with the percent effort commitment. This commitment should be at least a ten percent effort. Faculty critical to the design, development, implementation and refinement of the specialized curriculum essential to the training and didactic needs of the CRECD Program may be provided salary support in accordance with the percent effort of unique commitment. Salary support for Curriculum Advisory Committee members must be justified by their specific contributions to program development (see SPECIAL REQUIREMENTS). However, in general, it is assumed that many of these activities are within the normal scope expected of academic faculty and are supported by the applicant institution. The principal investigator and CRECD Program faculty may derive additional compensation from other Federal sources or awards provided the additional compensation does not exceed the maximum annual salary level for Federal employees (see INQUIRIES) and their total percent effort on all awards does not exceed 100 percent.

Compensation and expenses can be provided for external consultants and advisors.

Pre-doctoral appointees can be provided salaries/stipends of up to $20,000 per year plus fringe benefits commensurate with the institution's scale for persons of equivalent qualifications, experience and rank. Up to two years of support can be provided for the master’s degree. Salary and tuition may be applied only to those courses fulfilling requirements for the master’s degree.

Postdoctoral/Faculty appointees can be provided salaries of up to $75,000 per year plus fringe benefits commensurate with the institution's full_time salary scale for persons of equivalent qualifications experience and rank. Postdoctoral appointees may include junior faculty. Junior faculty will be considered those within seven years of their first faculty appointment. Up to two years of support can be provided for the master's degree.

The institution may supplement the NIH contribution to an appointee's salary up to a level that is consistent with the institution's salary scale. Institutional supplementation of a salary must not require extra duties or responsibilities that would interfere with the purpose of the award.

2. Other Expenses: Up to $20,000 in direct costs per year per trainee adjusted to the actual percent effort can be provided for the following types of expenses: (a) research expenses, such as supplies, equipment, and technical personnel; (b) tuition, fees, and books related to career development; (c) travel to research meetings or training; and (d) statistical services including personnel and computer time. These costs must be specifically documented for each individual candidate and must be specifically and directly related to the candidate's research activities.

3. Ancillary Personnel Support: Up to one full-time-equivalent in the personnel line may be appointed to provide administrative support for this program.

4. Facilities and Administrative Costs: These costs, which were formerly called indirect costs, will be reimbursed at 8 percent of modified total direct costs.

5. This R25 educational project grant, as administered by NIH, is not subject to the Streamlined Non_competing Application Process (SNAP). In general, this means that all reporting of budgetary information and CRECD Program progress is provided in greater detail. This R25 grant is subject to Expanded Authorities, the one exception is that carryover of funds from one fiscal year to the next must be approved by Program and Grants Administration staff.

6. In general, funds should not be budgeted for equipment.

SPECIAL REQUIREMENTS

1. The application must include a STATEMENT OF ELIGIBILITY of the applicant institution as a minority institution eligible for the CRECD Program with a cadre of doctorally qualified individuals to matriculate in the proposed program (see ELIGIBILITY REQUIREMENTS above).

2. A specialized curriculum leading to an accredited Master of Science in Clinical Research or an accredited Master of Public Health in a clinically relevant area, not otherwise available at the institution or other participating institutions, must be developed and linked to the training goals and objectives of the CRECD Program.

3. The principal investigator serves as the Program Director and should possess the leadership and administrative capabilities required to lead the development of a clinical research curriculum. A minimum ten percent effort is expected from the principal investigator. The Program Director must assemble and chair a permanent multidisciplinary Curriculum Advisory Committee (CAC) representing all of the disciplines, departments, schools, institutions etc. involved in this education and training program. The CAC will be responsible for the recruitment and selection of candidates for the CRECD Program; the establishment and review of effectiveness of the curriculum; the approval of the education and training plans (e.g., curriculum, research experiences, mentors) for each candidate; interim monitoring and evaluation of each candidate's progress with recommendations for changes in the plan, if necessary, or termination of a candidate who is not making adequate progress; and monitoring and evaluation of the overall effectiveness of the CRECD Program. The CAC will provide a summary report with each annual progress report that describes the Committee's actions, and discusses progress of the CRECD Program including evaluation of areas of strengths and weaknesses. The use of external advisors or an external advisory committee is encouraged.

4. All the mentors must be involved in clinical research or research methodologies clearly important to the clinical research focus and objectives of the proposed education and career development CRECD Program.

5. The curriculum must include a clinical research component as a required part of the program.

6. An evaluation plan must be provided for determining the performance of the processes and outcomes of the CRECD Program. This plan must include the parameters and criteria that will be used to evaluate the CRECD Program.

7. The budget must contain funds for the CRECD Principal Investigator and a co-director to attend a two day meeting twice yearly in Bethesda, MD. The purpose of these meetings will be for R25 grantees to present their progress in the planning and implementation of their programs and to discuss common issues. NIH may bring selected extramural and intramural staff as consultants/experts on scientific and training issues.

8. The NIH staff reserve the authority to recommend reductions in budget, withhold support, and to suspend and/or terminate the award if technical performance falls below acceptable standards for quality and timeliness.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103_43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm:
The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A_110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed program, the name, address, telephone, FAX, and E-mail numbers of the Program Director, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent to Dr. Julia Freeman listed under INQUIRIES below, by December 17, 2001.

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.pdf is to be used in applying for these grants. This version of PHS 398 is available in an interactive, searchable PDF format. Although applicants are strongly encouraged to begin using the 5/2001 revision of the PHS 398 as soon as possible, the NIH will continue to accept applications prepared using the 4/1998 revision until January 9, 2002. Beginning January 10, 2002, however, the NIH will return applications that are not submitted on the 5/2001 version. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

The RFA label available in the PHS 398 (rev. 5/01) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040_MSC 7710

BETHESDA, MD 20892_7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies must also be sent to:

Dr. C. William Angus
Scientific Review Administrator
National Center for Research Resources
6701 Rockledge Drive Room 6018
Bethesda, MD 20892-7965
Telephone: (301) 435-0812
FAX: (301) 480-3660
Email: angusw@ncrr.nih.gov

Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

If the application submitted in response to this RFA is substantially similar to a grant application already submitted to the NIH for review but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of essentially identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. An application, therefore, cannot be submitted in response to this RFA which is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Instructions for Preparing a CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS Grant Application:

Applications for CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS (R25) should use the Form PHS 398 and the modified instructions below, which take into account all of the special features and requirements of this grant.

1. Face Page: Use page AA of the form PHS 398. On Line 1 include the title that best represents the nature of your education and career development program. On line 2, provide the number (i.e., AR-01-009) and the title (i.e., CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS) of this RFA.

2. Description, Performance Site(s), Key Personnel: ((Page BB) of the form PHS 398): Complete as directed in the form PHS 398 instruction package; this should include the Program Director, Curriculum Advisory Committee Members, Mentors and other faculty participating in the CRECD Program. Please make sure that you denote each individual's degree and departmental affiliation (or equivalent) AND, if a consortia of institutions, institutional affiliation.

3. Table of Contents to be organized as follows:

a. Face Page
b. Description, Performance Site(s), Key Personnel
c. Table of Contents
d. Detailed Budget Page for First Year
e. Budget for Entire Proposed Period of Support
f. Budgets pertaining to Consortium/Contractual Arrangements
g. Other sources of institutional training, education, and career development support
h. Research Support of the principal investigator and the mentors that is specifically relevant to this Clinical Research Education and Career
Development Program
i. Biographical Sketches for:
_ Principal Investigator
_ Curriculum Advisory Committee Members
_ Mentors
_ Other Participating Faculty
_ Initial Trainees (if known at the time of application)
j. Statement of Eligibility (See SPECIAL REQUIREMENTS, item 1)
k. Education and Career Development Plan (Not to exceed 25 pages, excluding tables) with:
i. Purpose and Objectives
ii. Core Requirements including:
_specialized curriculum
_other didactic experiences
_research experiences
iii. Research Base/Resources and Facilities/Mentors
iv. Program Management including:
_ Principal Investigator
_ Curriculum Advisory Committee
_ Recruitment Strategies/Pool of Potential Students
- Selection Criteria for Choosing Students

_ Sample Individual Candidate Training Plans
_ Program Evaluation Plan
l. Human Subjects
m. Vertebrate Animals
n. Checklist
o. Appendices

4. Detailed Budget for the First Year: Use Form Page 4 (or DD) of the Form PHS 398.

Under PERSONNEL break out the individuals as follows with percent effort, salary and fringe benefits:
A. The Principal Investigator
B. Faculty being paid from the Grant
C. Pre-Doctoral Candidates by Name OR Position (when position is not filled)
D. Postdoctoral/Junior Faculty Candidates by Name OR Position (when position is not filled)
For Research and Development Costs, maintain a separation between predoctoral and postdoctoral candidates. For the budget categories other than salary specifically identify the requested costs under each budget category (e.g., supplies, travel) for each trainee by name or position (if the position is not filled), remembering that total for each individual cannot exceed $20,000.
E. Under travel, include funds for the Principal Investigator and one co-director to attend two meetings each year in Bethesda, MD, each meeting lasting two days.

5. Budget for the Entire Proposed Project Period of Support: Use Form Page 5 (or EE) of the Form PHS 398 and provide projected future year budgets as instructed in the Form PHS 398.

6. In a table, list all current and pending clinical research support and institutional training support available to the participating faculty, department(s), institution(s). Examples could include T32, R25 or K grants. Include funding source, complete identifying number, title of the program, name of the Principal Investigator, project period, number of training positions (doctoral, postdoctoral), and the amount of the award. For each grant listed, name only those participating faculty members who are also named in this application, and indicate their percent effort in those programs.

7. In a table, list all current and pending clinical research support relevant to this CRECD program available to the participating faculty, department(s), institutions(s). Examples could include R01 and other NIH mechanisms, contracts, VA, and private foundation grants. Include

funding source, complete identifying number, title of the program, name of the Principal Investigator, project period, number of training positions (doctoral, postdoctoral), and the amount of the award. For each grant listed, name only those participating faculty members who are also named in this application, and indicate their percent effort in those programs.

8. Biographical Sketches and Other Support: Provide biographical sketches using the forms provided in the PHS Form 398 package for the Principal Investigator, Curriculum Advisory Committee Members, Mentors, other participating faculty, and trainees (for those that are available).

9. Immediately before beginning the CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS Plan (See item 10, next), the application must include a STATEMENT OF ELIGIBILITY of the applicant institution as a Minority institution eligible for this program with a cadre of doctorally qualified individuals to matriculate in the proposed program (see ELIGIBILITY REQUIREMENTS and SPECIAL REQUIREMENTS, item 1).

10. CLINICAL RESEARCH EDUCATION AND CAREER DEVELOPMENT IN MINORITY INSTITUTIONS Plan:

a. Purpose and Objectives: In this section provide background, purpose and objectives of the CRECD Program.

b. Describe the requirements of this CRECD Program that each candidate is expected to complete that will lead to either an accredited Master of Science in Clinical Research or an accredited Master of Public Health in a clinically relevant area.

i. Specialized Curriculum: Describe the proposed core curriculum. Explain how the development and implementation of this curriculum is critically linked to the purpose and objectives of the CRECD Program and to the research career development of individual candidates.
Explain how this curriculum is distinguished from other curricula within the existing educational infrastructure and framework of the applicant/participating institution(s);

ii. Other Didactic Experiences: utilization of any existing curricula within the institution(s).

iii. Research Experiences: Outline briefly the kinds of research experiences each candidate will receive from the mentors of this CRECD Program that will prepare them as independent clinical investigators.

c. Research Base/Resources and Facilities/Mentors:

Research: Describe the research activities and experiences that will be offered to the students by the mentors participating in the program. Discuss how an active research environment will be sustained to meet the needs and objectives of the CRECD Program.

Resources and Facilities: Briefly describe the research infrastructure, access to patient populations, community populations etc., and facilities that are available and accessible to this CRECD Program.

Mentors: Describe the qualifications of the faculty research mentors including information on their experiences in conducting clinical research.

d. Program Leadership/Management:

i. Principal Investigator: Describe the qualifications and role of the Principal Investigator to provide leadership and coordination of the CRECD Program. A minimum of ten percent effort is required.

ii. Curriculum Advisory Committee (CAC): Describe how the CAC will function in providing oversight of the development, implementation and evaluation of recruitment strategies; recruitment and selection of candidates for the CRECD Program; establishment, implementation and evaluation of the core/specialized curriculum; approval of individual education and career development plan (e.g., curriculum, research/methodology experiences, mentors); interim monitoring and evaluation of each candidate's progress, including a determination of when a candidate has successfully completed the program, with recommendations for changes in the plan and, if necessary, termination of a candidate not making adequate progress; and monitoring of the overall effectiveness of the CRECD Program; role of external advisors.

iii. Recruitment and Selection Strategies: Within the multi-disciplinary research environments covered by this Clinical Research Education and Career Development in Minority institutions Program, describe the characteristics of candidates who will be selected for participation. Describe any recruiting strategies. Comment on the size of the candidate pool expected, note

any other institutional programs that might compete for this pool, and describe strategies for addressing this competition.

iv. Individual Candidate Training Plans: Provide examples of individual plans that the CRECD Program will employ to provide a unique education and career development experience for candidates, preparing them to design, implement and participate in highly inter-disciplinary, collaborative clinical research. Sample plans might address the needs of the combined degree doctoral student; a postdoctoral student who is an intern or resident; and a junior faculty member. Provide plans for conducting the required review process for each candidate.

v. CRECD Program Evaluation Plan: Describe the information that will be used in, the periods for, and criteria to be used in evaluating this CRECD Program.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review (CSR) and by the NIH program staff for adherence to the eligibility criteria for this RFA. Applications not responsive to this RFA WILL BE RETURNED to the applicant without review.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Office of Review of NCRR in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by an Advisory Board of an NIH Institute or Center.

All applications in response to this announcement will be evaluated for scientific and technical merit using the criteria noted below:

Review Criteria

1. Education Career Development Plan:

a. Purpose and Objectives:

_ clarity and importance of the CRECD Program's purpose and objectives

_ adequacy in meeting the NIH's intent of supporting education and career development programs that prepare candidates to participate as independent investigators in clinical research.

b. Core Requirements:

_ Degree to which all of the core requirements combined satisfy the training and career development objectives of the CRECD Program.

_ Quality of the process for evaluating each candidate's needs relative to the core requirements of the CRECD Program.

_ Adequacy of the subject matter and design of specialized curriculum; adequacy of the linkage of the specialized curriculum to the research training of the candidates; uniqueness of the specialized curriculum relative to other curricula available at the institution (s); adequacy of the faculty responsible for the specialized curriculum

_ Strength and availability of other didactic experiences available for each candidate's education and career development

_ Adequacy of the breadth and depth of research experiences available to candidates to achieve their multidisciplinary training objectives.

c. Research Base/Resources and Facilities/Mentors:

_ Adequacy of the research environment in the CRECD Program to support the proposed education and career development.

_ Adequacy of the available research infrastructure, patients, populations etc. to support the CRECD Program.

_ Quality of the mentors' research experience and likelihood of their success in training clinical scientists in the CRECD Program.

d. Program Leadership/Management:

_ Adequacy of the Program Director's experience and qualifications to lead and coordinate the CRECD Program.

_ Recruitment (Adequacy of the pool of candidates, and the criteria for selecting high quality candidates)

_ Curriculum Advisory Committee:
-- Appropriateness and experience of the membership
-- Adequacy of the CAC's involvement as a quality control in selecting candidates for the CRECD Program; establishing appropriate training plans for each candidate based on their individual needs and the CRECD Program Core Requirements; monitoring the progress of candidates and making midcourse corrections to improve the quality and effectiveness of each candidate's experiences; plans for evaluating a research thesis; terminating candidates for evident lack of performance or potential; and monitoring and evaluating the overall performance and effectiveness of the CRECD Program.

_ Individual Candidate Training Plans: Quality and completeness of the sample training plans relative to the purpose and objectives and core requirements of the CRECD Program.

_ Evaluation Plan: Adequacy of the criteria and process for evaluating the performance of the CRECD Program.

AWARD CRITERIA

Applications will compete for available funds with all other scored applications submitted in response to this RFA. Following the initial peer review for scientific and technical merit, the second level of review will be conducted by an NIH Advisory Council. The NIH will notify the applicant of the NIH Advisory Council's action. Final funding decisions are made by the NIH based on the quality of the proposed CRECD Program, as determined by peer review, the availability of funds and priorities of the NIH.

Schedule

Letter of Intent Receipt Date: December 19, 2001
Application Receipt Date: February 15, 2002
Peer Review Date: March/April 2002
Council Review: May/June 2002
Earliest Anticipated Start Date: September 2002

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o scientific merit (as determined by peer review)
- o availability of funds
- o programmatic priorities.

INQUIRIES

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.855 and 93.856. Awards are made under authorization of title III, Section 301 of the Public Health Service Act as amended. The Code of Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92 are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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